UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO COMPEL PRODUCTION OF DOCUMENTS ON DR. SCOTT AUGUSTINE'S PRIVILEGE LOG**

Plaintiffs have no stake in the relief sought in Defendantsô Motion, and have taken no position during this non-party discovery dispute. However, in light of 3Môs latest Motion, Plaintiffs feel compelled to file this Response to correct a fundamental misconception the Defendants continue to push regarding the nature of these lawsuits. 3M has not been subtle in its attempts to restyle these lawsuits as ñDr. Augustine v. 3M,ò hoping to convince this Court that 3M is an innocent victim of unfair business competition that will ñfuel years of litigation.ò[1] 3M declares its fear over the past few years has been the prospect of Dr. Augustine spreading lies about a product 3M maintains is safe - a fiction designed to distract from an alarming reality, namely that the Bair Hugger system was known by company officials to be unreasonably dangerous.

[redacted]

[redacted]

[1] See Defendantsô Motion, Doc. 184, p. 13.

[redacted] As set forth below, Plaintiffs' claims do not rely on statements made by Dr. Augustine or others, but on the facts acknowledged within the company as well as the conduct it willfully pursued. This conduct includes:

- Defendants secretly reduced the efficiency of the Bair Hugger filter without validating the safety of the change, and concealed this change from the FDA.
- Defendants were aware the inadequate filter was causing dangerous internal contamination in Bair Hugger units.
- Defendants' product engineers developed economically feasible design changes which would have helped mitigate the risk of bacterial infections, but these changes were rejected by management.
- Defendants publicly disputed a large volume of research regarding a Bair Hugger hazard, while acknowledging that hazard in internal discussions.
- Defendant sought to prevent any serious scientific inquiry into the infection risk from the Bair Hugger, and actively manipulated sponsored research while deleting unfavorable findings.

[2] Deposition of John Rock, at 86:9-13; 99:2-5, attached as Exhibit 1 to Declaration of Genevieve M. Zimmerman. All Exhibits referenced in this memorandum are attached to the Declaration of Genevieve M. Zimmerman.
[3] Id.
[4] 3MBH00053468, attached as Exhibit 2.

- Defendants are aware the scientific research justifying the use of the Bair Hugger has been disavowed by the authors involved in the research.

- Defendants now sell the VitaHEAT warming system, an air-free alternative product, and one of several advocated by Plaintiffs as a safer design.

A review of this evidence demonstrates that Plaintiffs' case is not driven by false allegations of a competitor, but on the events and facts acknowledged within the internal documents of the Defendants. For the Court's benefit, Plaintiffs present the following information to place the key allegations of the case into their proper context. The facts below show that any concern over Dr. Augustine's competition with 3M is entirely peripheral and irrelevant to the issues of safety raised in Plaintiffs' case.

FACTUAL BACKGROUND TO PLAINTIFFS' ALLEGATIONS

A. Critical Filter Changes Impact FDA Clearance and Patient Safety

Plaintiffs allege the filter currently in use on the Bair Hugger is inadequate to prevent the transmission of bacterial contamination. [redacted] The early Bair Hugger Model 500 series units filtered approximately 95% of .2 micron particles. That filter was the basis for the safety claims in the Bair Hugger's federal clearance. [redacted]

[5] Deposition of Dr. Daniel Sessler, at 64:21, attached as Exhibit 3.
[6] Id. at 64:23.

[redacted]

[7] 3MBH00047382, attached as Exhibit 4..
[8] 3MBH01897094, attached as Exhibit 5..
[9] Deposition of Gary Hansen, at 30:15, attached as Exhibit 6..
[10] 3MBH00022367, attached as Exhibit 7.
[11] 3MBH01031246, attached as Exhibit 8.
[12] Id.

[redacted]

[13] Id.
[14] Id.
[15] 3MBH00018311, attached at Exhibit 9.
[16] 3MBH00048067, attached at Exhibit 10.
[17] Id.
[18] Id.

[redacted]

B. The Undisclosed Filter Change Leads to Bacterial Contamination

In the years following the filter efficiency reduction on the Bair Hugger, the company began to receive reports from a variety of sources -- who had nothing to do with Dr. Augustine -- that Bair Huggers were harboring and incubating dangerous bacteria beyond the filter. For example, in a 2004 report published in Infection Control and Hospital Epidemiology entitled *Persistent Acinetobacter baumannii? Look Inside Your Medical Equipment*, the authors reviewed medical equipment in operating rooms

[19] 3MBH00107862, attached as Exhibit 11.
[20] 3MBH00126140, attached as Exhibit 12.
[21] 3MBH00132832, attached as Exhibit 13.
[22] 3MBH00008025, attached as Exhibit 14.
[23] Ex. 3 (Deposition of Daniel Sessler, at 34:21).

involved in an outbreak of dangerous infections.[24] The authors concluded "contaminated dust" from the interior of a Bair Hugger harbored a strain of A. baumannii bacteria responsible for the outbreak.[25] When the contaminated unit was removed, the outbreak stopped. [redacted]

After other similar reports, the company sent a letter in 2006 to certain customers who made inquiries on the subject of internal contamination. [redacted]

[24] 3MBH00018429-431, attached as Exhibit 15.
[25] Id.
[26] 3MBH00025739, attached as Exhibit 16.
[27] 3MBH00008941, attached as Exhibit 17.
[28] 3MBH00024592, attached as Exhibit 18.
[29] 3MBH00002647, attached as Exhibit 19.

[redacted]

[30] 3MBH00024633, attached as Exhibit 20.
[31] 3MBH00024678, attached as Exhibit 21.
[32] Id.
[33] Id.
[34] 3MBH00545125, attached as Exhibit 22.
[35] 3MBH00022625, attached as Exhibit 23.
[36] Id.
[37] Id.

[redacted]

[38] 3MBH00022877, attached as Exhibit 24.
[39] Id.
[40] Id.

[redacted]

[41] 3MBH00022625 at Ex. 23.
[42] 3MBH00008941, at Ex 17..

[redacted]

[redacted]

[redacted]

[43] 3MBH00031184, attached as Exhibit 25.
[44] Id.
[45] Id.
[46] Id.
[47] 3MBH00022625, Ex. 23.
[48] Deposition of Teri Woodwick-Sides, 139:18, attached at Exhibit 26.

[redacted]

D. Growing awareness of adverse scientific data

[redacted] Yet, the company was already aware of numerous peer-reviewed scientific studies which found evidence of Bair Huggers interfering with operating room airflow and creating a contamination risk. [redacted]

[49] 3MBH00022625, at Ex. 23.
[50] Id.
[51] 3MBH00005575, attached as Exhibit 27.
[52] 3MBH00052987, attached as Exhibit 28.
[53] Id.

[redacted]

Over the next few years, Defendants began to realize the scope of the problem in the face of growing evidence. [redacted]

Numerous scientists and surgeons recognized the risk of forced-air warming well before any litigation by patients. Indeed, prior to the first Bair Hugger lawsuit, McGovern, et al., ñfound a significant increase in deep joint infection, as demonstrated by an elevated odds ratio (3.8, p = 0.024), [during] a period when forced-air warming was used compared to a period when conductive fabric warming was used.ò McGovern, P., et al. *Forced-air warming and ultra-clean ventilation do not mix*. J Bone and Joint Surg-Br. 2011;93(11):1537ï 44.

[54] 3MBH00053468, attached as Exhibit 29.
[55] Id.
[56] 3MBH00109033, attached as Exhibit 30
[57] 3MBH00580475, attached as Exhibit 31.

3Môs attempts to discredit this study, along with numerous other studies cited in Plaintiffsô Master Complaint, have fallen flat at every step of this litigation. Setting aside the fact that the McGovern study was published in ñthe most valued [journal] for orthopaedic surgeons for over 125 years,ò[58] all the depositions taken to date have both confirmed and added to its alarming results. For example, Dr. McGovern repeatedly explained during his deposition ñthere was a 3.8 times more likely rate that a patient would incur a deep joint infection with the use of a forced-air warming device than with a conductive fabric warming device.ò[59] Co-authors Dr. Michael Reed and Professor Christopher Nachtsheim also gave testimony confirming the nature and importance of the studyôs findings. Dr. Reed highlighted the 3.8 risk ratio,[60] while Professor Nachtsheim discussed additional data demonstrating the change in antibiotic and thromboprophylaxis regimens did not confound the 3.8 odds risk ratio.[61] Dr. McGovern further explained the data collected post-publication continued to show that forced-air warming was associated with ña three times or more higher incidence of infectionò compared to air-free warming.[62] Dr. McGovern also testified -- contrary to 3Môs repeated yet baseless refrain -- that he ñdid not receive any compensation from Augustine é with respect to conducting the study.ò[63]

[58] See The Journal of Bone and Joint Surgery, available at http://jbjs.org/content/about-jbjs (last visited Jan. 22, 2017).
[59] Deposition of Dr. Paul McGovern, at 372:9-14, attached as Exhibit 32.
[60] Deposition of Mr. Michael Reed, at 219:12-18, attached as Exhibit 33.
[61] Deposition of Christopher Nachtsheim, at 328:14-348:2, attached as Exhibit 34.
[62] Depo. of Dr. Paul McGovern, at 415:8-20, at Ex. 32.
[63] Id., at 356:9.

E. Manufacture and manipulation of dubious research to deny Bair Hugger risk

[redacted]

[64] 3MBH00001557, attached as Exhibit 35.
[65] 3MBH00050756 , attached as Exhibit 36.
[66] Deposition of Daniel Sessler, p. 41:16-19, Ex. 3.
[67] Id., p. 66, at Ex. 3.

[redacted]

[68] Id., p. 68.
[69] 3MBH00024809, attached as Exhibit 37.
[70] 3MBH01224622, attached as Exhibit 38.
[71] 3MBH00130429, attached as Exhibit 39.

[redacted]

[72] Id.
[73] Id.
[74] Id.
[75] Id.
[76] 3MBH00083780, attached as Exhibit 40.
[77] Id.

[redacted]

[78] 3MBH01211442, attached as Exhibit 41.
[79] Id.
[80] 3MBH00051252, attached as Exhibit 42.
[81] 3MBH00575107, attached as Exhibit 43.
[82] 3MBH00575251, attached as Exhibit 44.

[redacted]

[83] Id.
[84] 3MBH00132501, at Ex. 24.
[85] Id.
[86] 3MBH01619270, attached as Exhibit 45.
[87] Id.
[88] 3MBH00555876, attached as Exhibit 46.
[89] 3MBH00130429, at Ex. 39.
[90] Id.

[redacted]

[91] Id.
[92] Id.
[93] Id.
[94] Id.
[95] Id.
[96] 3MBH00134035, attached as Exhibit 47.
[97] Id.
[98] 3MBH00107719, attached as Exhibit 48.

[redacted]

3M promoted the Bair Hugger forced air warming system to orthopedic surgeons. In so doing, 3M claimed the Bair Hugger maintains normothermia and that maintaining

[redacted]

[99] 3MBH01330588 , attached as Exhibit 49.
[100] Id.
[101] Id.
[102] Dr. Kurz is a leader in the research of normothermia and has written many articles that 3M relies upon to promote the Bair Hugger warming system.
[103] Deposition of Andrea Kurz, at 179:16, attached as Exhibit 50.
[104] Id. at 119:7, 13-19.

[redacted] 3M is ignoring the current science and relying on bad science, all the while falsely claiming the Bair Hugger system reduces the length of stay for patients in the hospital. [redacted][8]

Blowing hot air in the operating room negates any positive effect of HEPA air coming downward over the sterile operative site during an ultra-clean surgery. 3M has no credible scientific evidence to support its claims that the use of the Bair Hugger (placing a blower below the operating room table) reduces the incidence of wound infections or length of stay for patients.

[105] Id. at 179:4 to 179:6)
[106] Id. at 171:8; see also Scott AV, Stonemetz JL, Wasey JO, Johnson DJ, Rivers RJ, Koch CG, Frank SM. *Compliance with Surgical Care Improvement Project for Body Temperature Management (SCIP Inf-10) Is Associated with Improved Clinical Outcomes*. Anesthesiology. 2015;123:116ï 25
[107] Depo. of Daniel Sessler, at 118:21, at Ex. 3.
[108] Depo. of Andrea Kurz, at 87:22, at Ex. 50.

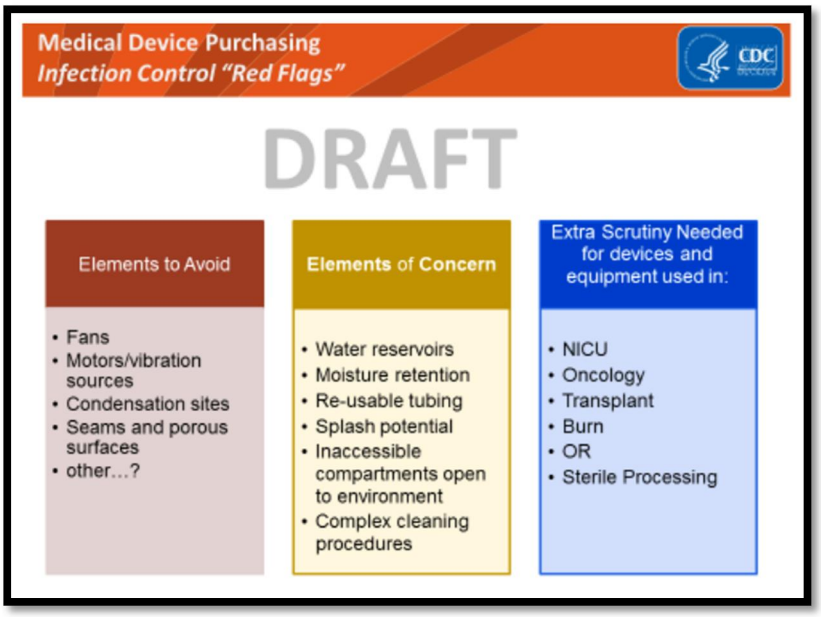
G. 3M now sells one of Plaintiff's proposed alternative designs

Plaintiffs also allege safer design alternatives to the Bair Hugger exist.[109] One such alternative is conductive warming blankets or mattresses such as theVitaHEAT resistive heat mattress. Recently, in October 2016, 3M announced it reached an agreement with VitaHEAT to be the exclusive distributor of its product in the United States.[110] The VitaHEAT UB3 product is a conductive warming mattress designed to be placed under a patient, allowing the clinician to adjust the temperature.[111] The makers of VitaHEAT note ñ[t]here is no forced air to warm up clinicians tending the patients.ò[112] And VitaHEAT touts ñCONDUCTIVE HEAT warms the patients without circulating air.ò[113] [redacted]

It appears that 3M has now seen the writing on the wall. Not only has the fundamental research justifying Bair Hugger been disavowed, but the U.S. Centers for Disease Control recently concluded equipment capable of circulating air should not be used in operating rooms. In 2015, the Healthcare Infection Control Practices Advisory

[109] See PlaintiffsôMaster Long Form Complaint at Paragraph 95.
[110] Exhibit 51, Article on Vitaheat/3M Contract.
[111] Exhibit 52, Vitaheat Product Information.
[112] Id.
[113] Id.
[114] Depo. of Daniel Sessler, at 125:2, at Ex. 3.
[115] Depo. of Daniel Sessler, at 125:2, at Ex. 3.

Committee (ñHICPAC) of the CDC stated that ñ[n]othing that blows air should be in an operating theater, if possible.ò[116] Furthermore, in 2016, HICPAC continued to discuss this issue and stated ñ[a]ir current generation: devices that blow air should probably not be situated in high-risk locationsò[117] HICPAC also prepared the below chart to guide medical device purchasers with respect to equipment to be used with patients:[118]



It is now clear there is no scientific justification for the use of the Bair Hugger in orthopedic surgeries, especially given the demonstrated hazards of these products, the established high risk nature of any surgery involving implantable prosthetic devices, and the availability of alternative devices.

[116] Exhibit 53, DRAFT CDC HICPAC Meeting Minutes, November 5-6, 2015, p. 27
[117] Id., at p. 29.
[118] Id.

CONCLUSION

Plaintiffs hope this partial exposition of the evidence developed to date helps the Court contextualize the Defendantsô Motion to Compel and dispel 3Môs theory that these lawsuits embody frivolous attacks from a competitor. Plaintiffsô claims are not based on Dr. Augustine nor any claims of business competition between him and 3M. Rather, this case is grounded on facts and science that demonstrate 3Môs awareness of deficiencies in the Bair Hugger system, an acknowledged lack of testing and proven inadequate filtration,, and troubling conduct in the face of known risks to patient safety. Plaintiffs look forward to presenting additional evidence concerning the nature of the risk with this Court, as revealed in the Defendantsô testimony and in the findings of Plaintiffsô experts.

Respectfully submitted,

Dated: January 26, 2017

CIRESI CONLIN L.L.P.

/s/ Michael V. Ciresi
Michael V. Ciresi (MN #0016949)
Jan M. Conlin (MN #0192697)
Ciresi Conlin LLP
225 S. 6th St., Suite 4600
Minneapolis, MN 55402
Phone: 612.361.8202
Email: MVC@CiresiConlin.com
JMC@CiresiConlin.com

MESHBESHER & SPENCE LTD.

/s/ Genevieve M. Zimmerman
Genevieve M. Zimmerman (MN #330292)
1616 Park Avenue South
Minneapolis, MN 55404
Phone: (612) 339-9121
Fax: (612) 339-9188
Email: gzimmerman@meshbesher.com

LEVIN PAPANTONIO, P.A.

/s/ Ben W. Gordon, Jr.
Ben W. Gordon (FL # 882836) ï Pro Hac Vice
J. Michael Papantonio (FL # 335924)
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996
Phone: (850) 435-7090
Fax: (850) 436-6090
Email: bgordon@levinlaw.com

Plaintiffs' Co-Lead Counsel